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Serial No.: 10/009,603

Confirmation No.: 4201

Filed: 11 December 2001

For: SUPPORT MATERIALS AND IMAGING METHOD FOR INTRAORAL DIAGNOSTIC PURPOSESAmendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1-16. (Canceled)

17. (Currently Amended) A deformable, curable, or film-forming composition comprising: a deformable, curable or film-forming support material, wherein the support material comprises a material that is (i) an impression material or film based on silicon, polyether-silicon, polyether, alginate or hydrocolloid, (ii) a polyethylene, polypropylene, poly(meth)acrylate, polyurethane, polycarbonate, polysulphide or polyvinylchloride plastic, (iii) a rubber composition, (iv) a polyvinylpyrrolidone-based or polyvinylalcohol-based hydrogel, or (v) a dental plaster preparation; and

at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material, wherein at least one diagnostically useful additive is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes.

18. (Canceled)

19. (Currently Amended) A The deformable, curable, or film-forming composition according to claim 17 comprising:

a deformable, curable or film-forming support material; and

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at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material, wherein at least one diagnostically useful additive is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes and wherein at least one in-which the diagnostically useful additive[[s]] is are present in micro-encapsulated form.

20. (Previously Presented) The composition according to claim 17, in which the diagnostic additives are contained in a quantity of from 0.0001 to 10 wt.-%.

21. (Previously Presented) The composition according to claim 17, in which the diagnostic additives are contained in a quantity of from 0.01 to 1 wt.-%.

22. (Canceled)

23. (Previously Presented) The composition according to claim 17 that is based upon N-alkylaziridinopolyether.

24. (Currently Amended) A process for making an intraoral diagnostic material comprising applying to a deformable, curable or film-forming support material containing no diagnostically useful additives at least one diagnostically useful additive that is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes, in a quantity effective for producing a diagnostic signal within or upon the surface of the support material or by binding

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of a detectable agent to the surface of the support material after the support material is applied to the oral cavity of a subject,

wherein the support material comprises a material that is (i) an impression material or film based on silicon, polyether-silicon, polyether, alginate or hydrocolloid, (ii) a polyethylene, polypropylene, poly(meth)acrylate, polyurethane, polycarbonate, polysulphide or polyvinylchloride plastic, (iii) a rubber composition, (iv) a polyvinylpyrrolidone-based or polyvinylalcohol-based hydrogel, or (v) a dental plaster preparation.

25. (Previously Presented) The process according to claim 24 in which the diagnostically useful additives are present in micro-encapsulated form.

26. (Previously Presented) The process according to claim 24 or 25, in which the signal is development of a visible color, a fluorescent signal, an ultraviolet signal, a phosphorescent signal or a luminescent signal.

27. (Previously Presented) The process according to claim 24 or 25 in which the diagnostically useful additives are used in a quantity of 0.0001 to 10 wt.-%.

28. (Canceled)

29. (Previously Presented) The process according to claim 24 in which the support material is an impression material based on N-alkylaziridinopolyether.

30. (Currently Amended) The process according to claim 27, in which the support material comprises:

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(A) 30 to 96.9999 wt.-% of at least one N-alkylaziridinopolyether with a molecular mass in the range of 1,000 to 20,000 g/mol and an aziridino equivalent mass in the range of 500 to 8,000 g/equivalent[[]],

(B) 1 to 10 wt.-% starter substances, which are suitable to effect the curing of the N-alkylaziridinopolyethers,

(C) 1 to 50 wt.-% organic diluting agents, and

(D) 1 to 50 wt.-% of at least one modifier, selected from the group consisting of fillers, dyes, pigments, thixotropes, flow improvers, polymeric thickeners, surfactants, fragrances, and flavourings.

31. (Currently Amended) A method for simultaneous examination of multiple intraoral loci for the presence of at least one specific substance comprising:

i) taking an impression of the oral cavity, or a part thereof, of a subject with ~~the a~~ deformable, curable, or film-forming composition according to claim 17, and comprising:
a deformable, curable or film-forming support material; and
at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material, wherein at least one diagnostically useful additive is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes;

ii) optionally applying to the oral cavity or to the impression at least one further diagnostically effective additive; and

iii) obtaining a signal from said diagnostically effective additive(s) at multiple intraoral loci.

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32. **(Previously Presented)** The method of claim 31, wherein the specific substance that is detected is one that is diagnostic for caries, early onset parodontitis, prepubertal parodontitis, juvenile parodontitis, rapid progressive parodontitis (RPP), adult parodontitis, refractory parodontitis, gingivitis, halitosis, infections with *Candida albicans*, *Candida krusei*, *Candida glabrata*, *Candida lusitanae*, *Candida dubliniensis* or cancer.
33. **(Previously Presented)** The method of claim 31, in which the specific substance is a substance that induces one or more cytokines.
34. **(Previously Presented)** The method of claim 33, in which the diagnostically effective additive is a monoclonal or polyclonal antibody that specifically binds to a lipopolysaccharide, a lipoarabinomannan, a peptidoglycan, a teichoic acid derivative, an extracellular polysaccharide, lipid A, interleukin-1, interleukin-2, interleukin-3, interleukin-4, interleukin-5, interleukin-6, interleukin-7, interleukin-8, tumor necrosis factor α , interferon α , interferon β , interferon γ , colony-forming factors M-CSF, epidermal growth factor, transforming growth factor α , the chemokine MCP, an arachidonic acid derivative, or prostaglandin E₂.
35. **(Previously Presented)** The method of claim 31, in which the diagnostically effective additive is a substrate for an enzyme selected from the group consisting of alkaline phosphatase, arylsulphatase, aspartataminotransferase, β -glucuronidase, cathepsin G, cathepsin B, cathepsin D, elastase, hyaluronidase, lactate-dehydrogenase, lysocyme, a matrix metal proteinase, a collagenase, a gelatinase, a tissue inhibitor of a metal proteinase, stomelysin, lactoferrin, tryptase and myeloperoxidase that produces a color reaction.
36. **(Previously Presented)** The method of claim 31, in which the diagnostically effective additive is a pH indicator or a calcium indicator.

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37. (Previously Presented) The method of claim 31, in which the image is transferred to a positive impression.
38. (Currently Amended) A. The deformable, curable, or film-forming composition of claim 17 comprising:
a deformable, curable or film-forming support material; and
at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material, wherein at least one diagnostically useful additive is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes.
wherein the composition that is in the form of polymerizable liquid that can be applied by spraying into the oral cavity or painting upon a surface of the oral cavity.
39. (Previously Presented) The composition of claim 17 in which at least one signal is development of a visible color, a fluorescent signal, an ultraviolet signal, a phosphorescent signal or a luminescent signal.
40. (Previously Presented) The composition of claim 17, in which the at least one diagnostically useful additive comprises an indicator selected from the group consisting of bromo phenol blue, Congo red, bromo cresol green, Oregon green derivatives, rhodol derivatives, redox indicators, such as methylene blue, 5-cyano-2,3-ditolytetrazolium chloride, 2-(4-iodophenyl)-3-(4-nitrophenyl)-5-phenyl-2H-tetrazolium chloride, 8-dimethylamino-2,3-benzophenoxazine, 1-methoxyphenazine methosulphate, 5-(3-carboxymethoxyphenyl)-2-(4,5-dimethylthiazolyl)-3-(4-

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sulphophenyl)tetrazolium, 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide, 3,3'-(3,3'-dimethoxy-4,4'-biphenylene)-bis[2-(4-nitrophenyl-5-phenyl)]-2H-tetrazolium chloride, nitrotetrazolium violet, phenazinmethosulphate, sodium-3'-[1-[(phenylamino)carbonyl]-3,4-tetrazolium]bis(4-methoxy-6-nitro)benzenesulphonic acid, phenazinethosulphate, Oregon green 488 BAPTA, calcium green, calcium orange, calcium crimson, 5-brom-2'-deoxyuridine, a p-nitroaniline derivative, a 2-naphthylamine derivative, a 7-amino-4-methylcoumarin derivative, a 7-amino-4-chloromethylcoumarin derivative, a 6-aminoquinoline derivative, a rhodamine derivative, 5,5'-dithiobis-(2-nitrobenzoic acid), a monobrombiman derivative, a tetramethylrhodamine derivative, an eosine derivative, an erythrosine derivative, a Texas red derivative, a coumarin derivative, a pyridyloxazol derivative, a benzofurazan derivative, a naphthaline derivative, a dansyl cysteine, a dansyl derivative, an aziridine derivative, a pyrene derivative and Coomassie blue.

41. **(Previously Presented)** The composition of claim 40, in which the indicator is covalently bound to an enzyme, a protein, a glycoprotein, a lipopolysaccharide, a polysaccharide, a polyclonal antibody, a monoclonal antibody, a DNA molecule, a RNA molecule, a cell organelle or a microorganism cell.

42. **(Previously Presented)** The composition of claim 17, in which the diagnostically useful additive is an enzyme selected from the group consisting of an oxidoreductase, a dehydrogenase, an oxidase, a peroxidase, a reductase, a monooxygenase, a dioxygenase, a transferase, a hydrolase, a lyase, an isomerase and a ligase.

43. **(Currently Amended)** The composition of claim 42, in which the diagnostically useful additive is an enzyme selected from the group consisting of lactate dehydrogenase, C₁-transferase, glycosyl transferase, glucosyltransferase, fructosyltransferase, aminotransferase, phospho-transferase esterase, a glycosidase, glucanase, fructanase, a peptidase, a

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dipeptidylpeptidase, Arg-gingipain, Lys-gingipain, a collagenase, a gelatinase, a cathepsin, an elastase, an amidase, a C-C-lyase, a C-O-lyase, a C-N-lyase, a C-S-lyase, an epimerase, a cis-trans-isomerase, an intramolecular transferase, a C-C-ligase, a C-O-ligase, a C-N-ligase, and a C-S-ligase.

44. (Previously Presented) The composition of claim 17, in which a plurality of diagnostically useful additives are present and each is micro-encapsulated.
45. (Previously Presented) The composition of claim 17, in which a plurality of diagnostically useful additives are present and at least one is micro-encapsulated and at least one is free in the support material.
46. (Currently Amended) A method for producing a diagnostic image of the oral cavity comprising:
- i) applying to the oral cavity, or a part thereof, of a subject a the deformable, curable, or film-forming composition of claim 17, and comprising:
 - a deformable, curable or film-forming support material; and
 - at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material, wherein at least one diagnostically useful additive is useful for intraoral locus-specific detection of pathogenic substances and/or microorganisms or for intraoral locus-specific detection of substances that indicate mouth diseases or healing processes;
 - ii) optionally applying to the oral cavity or to the impression at least one further diagnostically effective additive; and

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iii) imaging the diagnostic signal(s) produced by the diagnostically effective additive(s) thereby producing a diagnostic image of the oral cavity.

47. (Currently Amended) A deformable, curable, or film-forming composition comprising: a deformable, curable or film-forming support material, wherein the support material comprises a material that is (i) an impression material or film based on silicon, polyether-silicon, polyether, alginate or hydrocolloid, (ii) a polyethylene, polypropylene, poly(meth)acrylate, polyurethane, polycarbonate, polysulphide or polyvinylchloride plastic, (iii) a rubber composition, (iv) a polyvinylpyrrolidone-based or polyvinylalcohol-based hydrogel, or (v) a dental plaster preparation; and

at least one diagnostically useful additive for locus-specific and substance-specific intraoral diagnosis that provides such diagnostic result without a cultivation step and presents the diagnostic result by signal development in or upon the surface of the support material or by binding of a detectable agent to the support material.